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Polyoxyethylene Ethanol Monoesters of 5- (and 6-) Carboxy-4-Hexyl-2-Cyclohexene-1-Octanoic Acid Iodine Complex Pesticide Registration Standard

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This document contains information regarding reregistration of pesticide products containing the above chemical including how to register under a registration standard, regulatory position and rationale, and summarizes of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the Standard.

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Pesticide Registration Standard

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Polyoxyethylene ethanol monoesters of 5- (and 6-)carboxy-4-hexyl-2-cyclohexene-1-octanoic acid - Iodine Complex

Pesticide Registration Standard

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CHAPTER I: HOW TO REGISTER UNDER A REGISTRATION STANDARD

A. Organization of the Standard
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A. Organization of the Standard

This first chapter explains the purpose of a Registration Standard and summarizes the legal principles involved in registering or reregistering under a Standard. The second chapter sets forth the requirements that must be met to obtain or retain registration for products covered by this particular Registration Standard. In the remaining chapters, the Agency reviews the available data by scientific discipline, discusses the Agency's concerns with the identified potential hazards, and logically develops the conditions and requirements that would reduce those hazards to acceptable levels.

B. Purpose of the Standard

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that "no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive (and having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator [of EPA]." To approve the registration of a pesticide, the Administrator must find, pursuant to Section 3(c)(5) that:

"(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this Act;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

In making these findings, the Agency reviews a wide range of data which registrants are required to submit, and assesses the risks and benefits associated with the use of the proposed pesticide. But the established approach to making these findings has been found to be defective on two counts:

First, EPA and its predecessor agency, the United States Department of Agriculture (USDA), routinely reviewed registration applications on a "product by product" basis, evaluating each product-specific application somewhat independently. In the review of products containing similar components, there was little opportunity for a retrospective review of the full range of pertinent data available in Agency files and in the public literature. Thus the "product by product" approach was often inefficient and sometimes resulted in inconsistent or incomplete regulatory judgments.

Second, over the years, as a result of inevitable and continuing advances in scientific knowledge, methodology, and policy, the data base for many pesticides came to be considered inadequate by current scientific and regulatory standards. Given the long history of pesticide regulation in several agencies, it is even likely that materials may have been lost from the data files. When EPA issued new requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for hazard testing in 1978 (43 FR 29686, July 10, 1978 and 43 FR 37336, August 22, 1978), many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as was being required for new products. Because of this inconsistency, Congress directed EPA to re-register all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements, [See FIFRA Section 3(g)].

Facing the enormous job of rereviewing and calling-in new data for the approximately 35,000 current registrations, and realizing the inefficiencies of the "product by product" approach, the Agency decided that a new, more effective method of review was needed.

A new review procedure has been developed. Under it, EPA publishes documents called Registration Standards, each of which discusses a particular pesticide active ingredient. Each Registration Standard summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or reregistration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency does not now have, compliance with standards of toxicity, composition, labeling, and packaging, and satisfaction of the data compensation provisions of FIFRA Section 3(c)(1)(D).

The Standard will also serve as a tool for product classification. As part of the registration of a pesticide product, EPA may classify each product for "general use" or "restricted use" [FIFRA Section 3(d)]. A pesticide is classified for "restricted use" when some special regulatory restriction is

needed to ensure against unreasonable adverse effects to man or the environment. Many such risks of unreasonable adverse effects can be lessened if expressly-designed label precautions are strictly followed. Thus the special regulatory restriction for a "restricted use" pesticide is usually a requirement that it be applied only by, or under the supervision of, an applicator who has been certified by the State or Federal government as being competent to use pesticide safely, responsibly, and in accordance with label directions. A restricted-use pesticide can have other regulatory restrictions [40 CFR 162.11(c)(5)] instead of, or in addition to, the certified applicator requirement. These other regulatory restrictions may include such actions as seasonal or regional limitations on use, or a requirement for the monitoring of residue levels after use. A pesticide classified for "general use," or not classified at all, is available for use by any individual who is in compliance with State or local regulations. The Registration Standard review compares information about potential adverse effects of specific uses of the pesticide with risk criteria listed in 40 CFR 162.11(c), and thereby determines whether a product needs to be classified for "restricted use." If the Standard does classify a pesticide for "restricted use," this determination is stated in the second chapter.

C. Requirement to Reregister Under the Standard

FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all currently registered products as expeditiously as possible. Congress also agreed that reregistration should be accomplished by the use of Registration Standards.

Each registrant of a currently registered product to which this Standard applies, and who wishes to continue to sell or distribute his product in commerce, must apply for reregistration. His application must contain proposed labeling that complies with this Standard.

EPA will issue a notice of intent to cancel the registration of any currently registered product to which this Standard applies if the registrant fails to comply with the procedures for reregistration set forth in the Guidance Package which accompanies this Standard.

D. "Product Specific" Data and "Generic" Data

In the course of developing this Standard, EPA has determined the types of data needed for evaluation of the properties and effects of products to which the Standard applies, in the disciplinary areas of Product Chemistry, Environmental Fate, Toxicology, Residue Chemistry, and Ecological Effects. These determinations are based primarily on the data Guidelines proposed in 43 FR 29696, July 10, 1978; 43 FR 37336, August 22, 1978; and 45 FR 72948, November 3, 1980, as applied to the use patterns of the products to which this Standard applies. Where it appeared that data from a normally applicable Guidelines requirement was actually unnecessary to evaluate these products, the Standard indicates that the requirement has been waived. On the other hand, in some cases studies not required by the Guidelines may be needed because of the particular composition or use pattern of products the Standard covers; if so,

the Standard explains the Agency's reasoning. Data guidelines have not yet been proposed for the Residue Chemistry discipline, but the requirements for such data have been in effect for some time and are, the Agency believes, relatively familiar to registrants. Data which we have found are needed to evaluate the registrability of some products covered by the Standard may not be needed for the evaluation of other products, depending upon the composition, formulation type, and intended uses of the product in question. The Standard states which data requirements apply to which product categories. (See the third chapter.) The various kinds of data normally required for registration of a pesticide product can be divided into two basic groups:

1. Data that are product specific , i.e. data that relates only to the the properties or effects of a product with a particular composition (or a group of products with closely similar composition); and

2. Generic data that pertain to the properties or effects of a particular ingredient, and thus is relevant to an evaluation of the risks and benefits of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition.

The Agency requires certain "product specific" data for each product to characterize the product's particular composition and physical/chemical properties (Product Chemistry), and to characterize the product's acute toxicity (which is a function of its total composition). The applicant for registration or reregistration of any product, whether it is a manufacturing-use or end-use product, and without regard to its intended use pattern, must submit or cite enough of this kind of data to allow EPA to evaluate the product. For such purposes, "product specific" data on any product other than the applicant's is irrelevant, unless the other product is closely similar in composition to the applicant's. (Where it has been found practicable to group similar products for purposes of evaluating, with a single set of tests, all products in the group, the Standard so indicates.) "Product specific" data on the efficacy of particular end-use products is also required where the exact formulation may affect efficacy and where failure of efficacy could cause public health problems.

All other data needed to evaluate pesticide products concerns the properties or effects of a particular ingredient of products (normally a pesticidally active ingredient, but in some cases a pesticidally inactive, or "inert", ingredient). Some data in this "generic" category are required to evaluate the properties and effects of all products containing that ingredient [e.g., the acute LD-50 of the active ingredient in its technical or purer grade; see proposed 40 CFR 163.81-1(a), 43 FR 37355].

Other "generic" data are required to evaluate all products which both contain a particular ingredient and are intended for certain uses (see, e.g., proposed 40 CFR 163.82-1, 43 FR 37363, which requires subchronic oral testing of the active ingredient with respect to certain use patterns only). Where a particular data requirement is use-pattern dependent, it will apply to each end-use product

which is to be labeled for that use pattern (except where such end-use product is formulated from a registered manufacturing-use product permitting such formulations) and to each manufacturing-use product with labeling that allows it to be used to make end-use products with that use pattern. Thus, for example, a subchronic oral dosing study is needed to evaluate the safety of any manufacturing-use product that legally could be used to make an end-use, food-crop pesticide. But if an end-use product's label specified it was for use only in ways that involved no food/feed exposure and no repeated human exposure, the subchronic oral dosing study would not be required to evaluate the product's safety; and if a manufacturing-use product's label states that the product is for use only in making end-use products not involving food/feed use or repeated human exposure, that subchronic oral study would not be relevant to the evaluation of the manufacturing-use product either.

If a registrant of a currently registered manufacturing-use or end-use product wishes to avoid the costs of data compensation [under FIFRA Section 3(c)(1)(D)] or data generation [under Section 3(c)(2)(B)] for "generic" data that is required only with respect to some use patterns, he may elect to delete those use patterns from his labeling at the time he reregisters his product. An applicant for registration of a new product under this Standard may similarly request approval for only certain use patterns.

E. Data Compensation Requirements under FIFRA 3(c)(1)(D)

Under FIFRA Section 3(c)(1)(D), an applicant for registration, reregistration, or amended registration must offer to pay compensation for certain existing data the Agency has used in developing the Registration Standard. The data for which compensation must be offered is all data which are described by all the following criteria:

1. The data were first submitted to EPA (or to its predecessor agencies, U.S. Department of Agriculture (USDA) or Food and Drug Administration (FDA), on or after January 1, 1970;

2. The data were submitted to EPA (or USDA or FDA) by some other applicant or registant in support of an application for an experimental use permit, an amendment adding a new use to a registration, or for registration, or to support or maintain in effect an existing registration;

3. They are the kind of data which are relevant to the Agency's decision to register or reregister the applicant's product under the Registration Standard, taking into account the applicant's product's composition and intended use pattern(s);

4. The Agency has found the data to be valid and usable in reaching regulatory conclusions; and

5. They are not data for which the applicant has been exempted by FIFRA Section 3(c)(2)(D) from the duty to offer to pay compensation. (This exemption applies to the "generic" data concerning the safety of an active ingredient of the applicant's product, not to "product specific" data. The exemption is available only to applicants whose product is labeled for end-uses for which the active ingredient in question is present in the applicant's product because of his use of another registered product containing that active ingredient which he purchases from another producer.)

An applicant for reregistration of an already registered product under this Standard, or for registration of a new product under this Standard, accordingly must determine which of the data used by EPA in developing the Standard must be the subject of an offer to pay compensation, and must submit with his application the appropriate statements evidencing his compliance with FIFRA Section 3(c)(1)(D).

An applicant would never be required to offer to pay for "product specific" data submitted by another firm. In many, if not in most cases, data which is specific to another firm's product will not suffice to allow EPA to evaluate the applicant's product, that is, will not be useful to the Agency in determining whether the applicant's product is registrable. There may be cases, however, where because of close similarities between the composition of two or more products, another firm's data may suffice to allow EPA to evaluate some or all of the "product specific" aspects of the applicant's product. In such a case, the applicant may choose to cite that data instead of submitting data from tests on his own product, and if he chooses that option, he would have to comply with the offer-to-pay requirements of Section 3(C)(1)(D) for that data.

Each applicant for registration or reregistration of a manufacturing-use product, and each applicant for registration or reregistration of an end-use product, who is not exempted by FIFRA Section 3(c)(2)(D), must comply with the Section 3(c)(1)(D) requirements with respect to each item of "generic" data that relates to his product's intended uses.

A detailed description of the procedures an applicant must follow in applying for reregistration (or new registration) under this Standard is found in the Guidance Package for this Standard.

F. Obtaining Data to Fill "Data Gaps"; FIFRA 3(c)(2)(B)

Some of the kinds of data EPA needs for its evaluation of the properties and effects of products to which this Standard applies have never been submitted to the Agency (or, if submitted, have been found to have deficiencies rendering them inadequate for making registrability decisions) and have not been located in the published literature search that EPA conducted as part of preparing this Standard. Such instances of missing but required data are referred to in the Standard as "data gaps".

FIFRA Section 3(c)(2)(B), added to FIFRA by the Congress in 1978, authorizes EPA to require registrants to whom a data requirement applies to generate (or otherwise produce) data to fill such "gaps" and submit those data to EPA. EPA must allow a reasonably sufficient period for this to be accomplished. If a registrant fails to take appropriate and timely steps to fill the data gaps identified by a section 3(c)(2)(B) order, his product's registration may be suspended until the data is submitted. A mechanism is provided whereby two or more registrants may agree to share in the costs of producing data for which they are both responsible.

The Standard lists, in the third chapter, the "generic" data gaps and notes the classes of products to which these data gaps pertain. The Standard also points out that to be registrable under the Standard, a product must be supported by certain required "product specific" data. In some cases, the Agency may possess sufficient "product specific" data on one currently registered product, but may lack such data on another. Only those Standards which apply to a very small number of currently registered products will attempt to state

definitively the " product specific" data gaps on a "product by product" basis. (Although the Standard will in some cases note which data that EPA does possess would suffice to satisfy certain "product specific" data requirements for a category of products with closely similar composition characteristics.)

As part of the process of reregistering currently registered products, EPA will issue Section 3(c)(2)(B) directives requiring the registrants to take appropriate steps to fill all identified data gaps -- whether the data in question are "product specific" or "generic" -- in accordance with a schedule.

Persons who wish to obtain registrations for new products under this Standard will be required to submit (or cite) sufficient "product specific" data before their applications are approved. Upon registration, they will be required under Section 3(c)(2)(B) to take appropriate steps to submit data needed to fill "generic" data gaps. (We expect they will respond to this requirement by entering into cost-sharing agreements with other registrants who previously have been told they must furnish the data.) The Guidance Package for this Standard details the steps that must be taken by registrants to comply with Section 3(c)(2)(B).

Registrants are reminded that Section 6(a)(2) of FIFRA requires you <u>at any time</u> to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

G. <u>Amendments to the Standard</u>

Applications for registration which propose uses or formulations that are not presently covered by the Standard, or which present product compositions, product chemistry data, hazard data, toxicity levels, or labeling that do not meet the requirements of the Standard, will automatically be considered by the

Agency to be requests for amendments to the Standard. In response to such applications, the Agency may request additional data to support the proposed amendment to the Standard, or may deny the application for registration on the grounds that the proposed product would cause unreasonable adverse effects to the environment. In the former case, when additional data have been satisfactorily supplied, and providing that the data do not indicate the potential for unreasonable adverse effects, the Agency will then amend the Standard to cover the new registration.

Each Registration Standard is based upon all data and information available to the Agency's reviewers on a particular date prior to the publication date. This "cut-off" date is stated at the beginning of the second chapter. Any subsequent data submissions and any approved amendments will be incorporated into the Registration Standard by means of addenda, which are available for inspection at EPA in Washington, D.C., or copies of which may be requested from the Agency. When all the present "data gaps" have been filled and the submitted data have been reviewed, the Agency will revise the Registration Standard. Thereafter, when the Agency determines that the internally maintained addenda have significantly altered the conditions for registration under the Standard, the document will be updated and re-issued.

While the Registration Standard discusses only the uses and hazards of products containing the designated active ingredient(s), the Agency is also concerned with the potential hazards of some inert ingredients and impurities.

Independent of the development of any one Standard, the Agency has initiated the evaluation of some inert pesticide ingredients. Where the Agency has identified inert ingredients of concern in a specific product to which the Standard applies, these ingredients will be pointed out in the Guidance Package.

CHAPTER II: REGULATORY POSITION AND RATIONALE

A. Introduction
B. Description of Chemical
C. Classification under Minor Use
D. Regulatory Position
E. Regulatory Rationale
F. Criteria for Registration Under the Standard
G. Acceptable Ranges and Limits
H. Required Labeling
I. Tolerance Reassessment

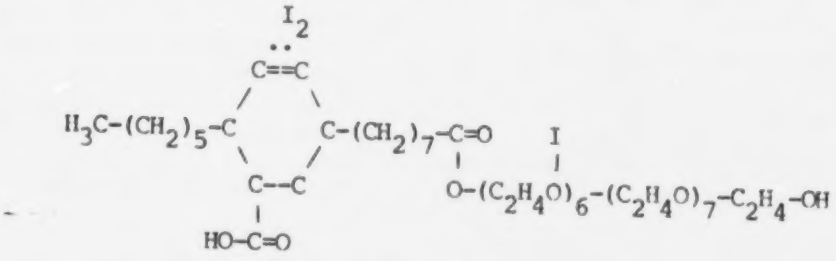
A. Introduction

This chapter presents the Agency's regulatory position and rationale based on an evaluation of all registered products containing polyoxyethylene ethanol monoesters of 5-(and 6-) carboxy-4-hexyl-2-cyclohexene-1-octanoic acid - iodine complex as the sole active ingredient. After briefly describing the chemical, this chapter presents the regulatory position and rationale, the criteria for registration of products containing this chemical, labeling considerations and a tolerance reassessment. A summary of data requirements is contained in chapter III. A discussion of the data upon which this regulatory position is based is presented in each of the disciplinary chapters, IV through VIII.

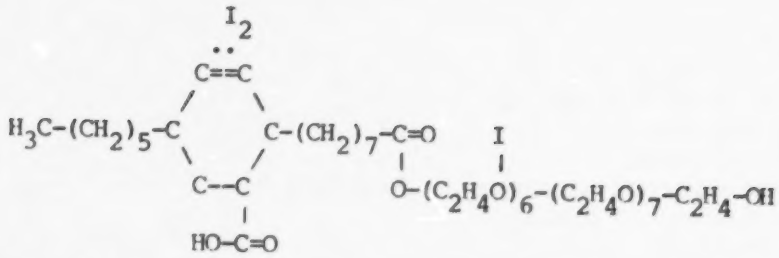
B. Description of Chemical

Polyoxyethylene ethanol monoesters of 5-(and 6-)carboxy-4-hexyl-2-cyclohexene-1-octanoic acid - iodine complex is the active ingredient, found at concentrationof 4.3 percent, in a low foaming iodophor industrial sanitizer of food contact surfaces (eg. food processing equipment), dishes, glasses and utensils.

The structural formulas for this active ingredient are:



Polyoxyethylene ethanol monoesters of 5-carboxy-4-hexyl-2-cyclohexene-1-octanoic acid - iodine complex



Polyoxyethylene ethanol monoesters of 6-carboxy-4-hexyl-2-cyclohexene-1-octanoic acid - iodine complex

Prior to application, the 4.3 percent active ingredient in the formulated product is diluted in water at a rate of 1:657 to yield 25 ppm of the bactericidal iodine. The diluted product is applied to pre-cleaned food contact surfaces by either spraying or swabbing and to pre-cleaned dishes and utensils by dipping, swabbing or spraying. The diluted product must remain on the treated surface to maintain efficacy and to prevent recontamination of the treated surface.

This product is not currently marketed as a manufacturing-use product. Only one registrant (Pennwalt Corporation) exists for the sole registered end-use product containing this chemical.

C. Classification Under Minor Use

End-use products (usually those with less than 25,000 pounds of active ingredient per year) from which exposure is expected to be minimal, based on use rates and patterns, may be classified by the Agency to be minor use chemicals.

After extensive inquiries, the Agency has concluded that this product has never been marketed. Accordingly, this is a minor use chemical at this time. Both because of the minor use classification of the end-use product and because no technical chemical is currently marketed, the environmental fate data requirements have been reserved in this Standard. The Agency has concluded that reservation of the requirement for environmental fate testing is justified because the use patterns of the end-use product containing this chemical are likely to result in a minimal potential exposure to humans and wildlife.

D. Regulatory Position

Based on a review of the available scientific data and other relevant information on polyoxyethylene ethanol monoesters of 5-(and 6-)carboxy-4-hexyl-2-cyclohexene-1-octanoic acid - iodine complex, the Agency has made the following determinations:

1. Pesticide products containing this active ingredient may be registered, subject to the terms and conditions specified in this Standard.

2. None of the risk criteria found in section 162.11(a) of Title 40 U.S. Code of Federal Regulations has been met or exceeded for this active ingredient.

3. No unreasonable adverse effects have been identified for this active ingredient when used in accordance with label directions and limitations.

4. Because residues on food contact surfaces may result in dietary exposure to this chemical, a food additive regulation for this chemical must be obtained from the Food and Drug Administration (FDA) as a condition of reregistration. The present registration of this chemical will be cancelled if a food additive regulation cannot be obtained for this chemical.

5. Additional data, specified in chapter III, must be developed or agreed to be developed to maintain the existing registration or to permit new registrations.

E. Regulatory Rationale

Based on the available product chemistry, acute toxicology and efficacy data, the Agency has determined that hazards associated with the uses of this chemical are very small.

Exposure to this chemical, occuring via consumption of residues remaining on the food contact surface, via worker exposure to the formulated product, or in diluting the formulated product, will be very small.

Section 409 of the Federal Food, Drug and Cosmetic Act requires that a food additive regulation be obtained for all chemicals whose use may result in residues on food contact surfaces. In a memorandum of agreement between the Agency and the Department of Health, Education and Welfare (36 FR 24234), both agencies agreed that the Food and Drug Administration (FDA) will have the responsibilty for reviewing " petitions for food additive regulations to permit the use of sanitizers on food contact surfaces." FDA's role, therefore, is to review the safety of residues which may occur from the use of anti-microbials on food contact surfaces, while EPA's role is to review the information related to the pesticidal uses of sanitizers on these surfaces.

Based on the uses of this chemical, the Agency has concluded that the dietary exposure lies within the purview of section 409 of the Federal Food, Drug and Cosmetic Act. The Agency, therefore, defers the dietary risk assessment to FDA. The Agency will limit its assessment to applicator or user risk.

Current FDA policy only permits the use of sanitizers of food contact surfaces which have received a food additive regulation. In the past, EPA, charged with regulating pesticides used on food contact surfaces, registered food contact surface sanitizers which did not have a food additive regulation. Past Agency policy required that food contact surfaces treated with uncleared sanitizers

receive a potable water rinse to remove residues. FDA, by contrast, does not permit the use of a potable water rinse after sanitization and requires that the sanitizers themselves be the terminal or last rinse of the food contact surface. FDA contends that the use of a final rinse to remove residues of the sanitizer will counteract the antimicrobial effect of the sanitizer and may also lead to recontamination of the treated surface.

EPA concurs with FDA's policy and is currently in the process of coordinating its scientific review process with that agency. As with this chemical, EPA will require all future applicants for registration of food contact surface sanitizers to obtain a food additive regulation prior to registration. The Agency has also decided that all presently registered food contact surface sanitizers must be cleared by a food additive regulation. Registrants of sanitizers which are not cleared for use on food contact surfaces will be required to obtain a food additive regulation at the time of reregistration. At the time of reregistration, all chemicals not cleared for use on food contact surfaces must remove any labeling which recommends their use as a terminal sanitizing rinse. In addition, at the time of reregistration, all chemicals which are cleared for use on food contact surfaces previously recommending the use of a terminal potable water rinse must remove that recommendation.

The Agency has concluded that the limited toxicity and exposure information available is sufficient to evaluate the applicator risks associated with the uses of this chemical. This decision is based on two factors: (1) that available acute toxicity data are sufficient to assess the risks from acute exposure and (2) that the likelihood of significant chronic exposure is so low that chronic toxicity data are not necessary to make a regulatory determination of acceptable risk.

Based on the review of the end-use product acute toxicity data, the Agency has concluded that proper labeling is sufficient to adequately mitigate any acute toxicity risks.

The determination that expected chronic exposure is low is based on the combination of low concentration of the active ingredient in the formulated product, the high dilution in the use solution, the staining and irritating properties of the formulated product, and the required use of goggles and gloves when using both the concentrated and diluted solution of this chemical. Based on this low expected chronic exposure, the Agency has concluded that chronic toxicity data are not required for this chemical and that the risk of a chronic toxic effect is very low.

Since the indoor uses preclude significant environemtal exposure, except as a diluted, spent solution which drains into the sanitary sewer, the Agency has determined that (1) no ecological effects studies are necessary and (2) activated sludge and hydrolysis tests are sufficient to evaluate the environmental fate of this chemical. Because of the minor use status of this

chemical, the Agency has further decided to reserve its request for environmental fate data until the total production of this active ingredientin this and future products containing this chemical reaches 25,000 pounds per year.

In light of the determination of acceptable risk, the Agency has concluded that it should continue the registration for this chemical, provided that a food additive regulation is obtained for this chemical. The present registration of this chemical will be cancelled if a food additive regulation cannot be obtained for this chemical.

The Agency has also concluded that it will consider the registration of other formulations of this chemical, provided that, prior to registration, (1) a determination is made by FDA as to whether an additional food additive regulation is required for their specific formulation and (2), if required, that they also obtain a food additive regulation.

F. Criteria for Registration Under the Standard

To be subject to this Standard, products must meet the following conditions:

- contain polyoxyethylene ethanol monoesters of 5- (and 6-) carboxy-4-hexyl-2-cyclohexene-1-octanoic acid - iodine complex as the sole acive ingredient; and

- bear required labeling; and

- conform to the acute toxicity limits, product composition and use pattern requirements stated in section 5 below.

The applicant for registration or reregistration of products subject to this Standard must comply with all terms and conditions described in this Standard including a commitment to fill data gaps on a time schedule specified by the Agency and, when applicable, offering to pay compensation to the extent required by 3(c)(1)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, 7 U.S.C. 136a(c)(1)(D). As discussed in chapter I, applicants for registration under this Standard must contact the Registration Division for specific instructions, including updated information contained in the guidance package on data requirements and the company whose data must be cited and to whom compensation must be offered.

G. Acceptable Ranges and Limits

1. Manufacturing-Use Products

No manufacturing-use products are currently registered. Because the active ingredient is made during the formulation of the end-use product, the Agency has determined that the production of the currently registered end-use product

falls within the definition of an integrated formulation system. A manufacturing-use product of any concentration of this chemical is registrable when labeled in accordance with the results of the appropriate product chemistry and toxicity testing.

2. End-Use Products

a. Product Composition Standard

Currently the Agency has no information on acceptable ranges and limits for the product composition of end-use products containing this chemical. To be covered under this Standard, end-use products containing this chemical must propose acceptable ranges and limits for both active and inert ingredients.

b. Acute Toxicity Limits

The Agency will consider registration of end-use products containing this chemical under a general-use classification, regardless of their toxicity category, provided that they bear appropriate precautionary labeling.

Products whose acute toxicity potentially places them in a restricted-use classification may be classified for general-use if these pestcides bear labeling which will reduce the acute hazard of that product to one which is appropriate for the general-use classification.

c. Use Patterns and Application Methods

To be registered under this standard, end-use products containing this chemical must be labeled as a food contact surface sanitizer.

H. Required Labeling

To be considered under this Standard, end-use products must bear directions for use as an industrial, indoor sanitizer to be used on food contact surfaces, dishes, glasses and utensils without a terminal rinse. Spent use-dilutions of this chemical should be disposed through the sanitary sewer. In addition, end-use products must bear precautionary labeling which requires the use of goggles (face shield) and gloves. All other specific labeling is presented in the guidance package for this chemical.

I. Tolerance Reassessment

While no tolerance is required for this chemical, provisions of the Federal Food Drug and Cosmetic Act require the establishment of a food additive regulation for the use of this chemical on food contact surfaces, dishes, glasses and utensils. (See 21 CFR section 178.1010) A food additive regulation must be obtained for this chemical for the registration to remain in effect.

CHAPTER III: SUMMARY OF DATA REQUIREMENTS AND DATA GAPS

A. Introduction
B. Group A Charts: Generic Data Requirements
C. Group B Charts: Manufacturing-Use Data Requirements
D. Group C Charts: End-Use Product-Specific Data Requirements

A. Introduction

Applicants for registration of end-use polyoxyethylene ethanol monoesters of 5-(and 6-)carboxy-4-hexyl-2-cyclohexene-1-octanoic acid - iodine complex products must cite or submit the following information on the physical/chemical properties, composition, fate and toxicity of the proposed product. Data in this Standard that satisfy registration requirements may be cited, if the applicant establishes that the proposed product is substantially similar to another product for which the Agency has received acceptable acute toxicity tests. Data may be cited provided compensation has been offered to the submitters of these studies. The Agency will consider both active and inert ingredients in the determination of substantially similar products. (See chapter I for discussion of substantially similar products). Before each requirement is listed the section of the Proposed Guidelines which describes the type of data and when it is required [43 FR, 29696 of July 10, 1978; and 43 FR, No. 163, 37336 of August 22, 1978]. Justification for the test requirement is provided in the Guidelines. Areas where this Standard differs from the Guidelines are discussed in the Regulatory Rationale section of chapter II. Applicants for the reregistration of end-use polyoxyethylene ethanol monoesters of 5- (and 6-)carboxy-4-hexyl-2-cyclohexene-1-octanoic acid -iodine complex must submit all information identified as data gaps (see charts). A discussion of why data additional to that already submitted are necessary, or why data normally required are not necessary for this chemical, are explained in footnotes to the charts. The footnotes to the charts offer an explanation of additional data requirements or data waivers outside of the guidelines. The data requirements specified are the minimum that will be required.

DATA REQUIREMENTS CHART A

Polyoxyethylene Ethanol Monoesters of 5- (and 6-) Carboxy- 4-Hexyl-2-Cyclohexene-1-Octanoic Acid - Iodine Complex

Generic Data Requirements: ENVIRONMENTAL FATE

Guidelines Citation	Name of Test	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? If so, due when?
163.62-7(b)	Hydrolysis	Technical Grade of Active Ingredient	no	-	Reserved 1/
163.62-8(g)	Activated Sludge	Technical Grade of Active Ingredient	no	-	Reserved 1/2/

These data requirements are current as of September, 1981. Refer to the guidance package for updated requirements.

1. Currently there is no manufacturing-use product for this chemical. Submission of tests normally required of a registered manufacturing-use chemical will not be requested until such a time as the Agency receives an application for registration of a manufacturing-use chemical and its production reaches or exceeds 25,000 pounds of A.I. per year. The Agency will monitor production of products containing this chemical under the authority of section 7 FIFRA. All protocols should be submitted and reviewed by the Agency prior to initiation of this test.

2. This study will be required pending development of an acceptable protocol.

September, 1981

DATA REQUIREMENTS CHART A

Polyoxyethylene Ethanol Monoesters of 5- (and 6-) Carboxy- 4-Hexyl-2-Cyclohexene-1-Octanoic Acid - Iodine Complex

Generic Data Requirements: TOXICOLOGY

Guidelines Citation	Name of Test	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? If so, due when?
163.81-1	Acute Oral Toxicity	Technical Grade of Active Ingredient	no	-	Reserved 1/
163.81-2	Acute Dermal Toxicity	Tech. Grade of A.I.	no	-	Reserved 1/
163.81-3	Acute Inhalation Toxicity	Tech. Grade of A.I.	no	-	Reserved 1/
163.81-4	Primary Eye Irritation	Tech. Grade of A.I.	no	-	Reserved 1/
163.81-5	Primary Skin Irritation	Tech. Grade of A.I.	no	-	Reserved 1/
163.81-6	Dermal Sensitization	Tech. Grade of A.I.	no	-	Reserved 1/

These data requirements are current as of September, 1981. Refer to the guidance package for updated requirements.

1. Currently there is no manufacturing-use product for this chemical. Submission of tests normally required of a registered manufacturing-use chemical will not be requested until such time as the Agency receives an application for registration of a manufacturing-use chemical.

September, 1981

DATA REQUIREMENTS CHART A

Polyoxyethylene Ethanol Monoesters of 5- (and 6-) Carboxy- 4-Hexyl-2-Cyclohexene-1-Octanoic Acid - Iodine Complex

Generic Data Requirements: RESIDUE CHEMISTRY

Guidelines Citation	Name of Test	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? If so, due when?

Sanitizers containing this chemical must obtain a food additive regulation for this chemical.

These data requirements are current as of September, 1981. Refer to the guidance package for updated requirements.

September, 1981

DATA REQUIREMENTS CHART B

Polyoxyethylene Ethanol Monoesters of 5- (and 6-) Carboxy- 4-Hexyl-2-Cyclohexene-1-Octanoic Acid - Iodine Complex

Manufacturing-Use Data Requirements: PRODUCT CHEMISTRY

Guidelines Citation	Name of Test	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? If so, due when?
163.61-3	Product Identitiy & Disclosure of Ingredients	Each Product	no	-	Reserved 1/ 2/
163.61-4	Description of Manufacturing Process	Each Product	no	-	Reserved 1/ 2/
163.61-5	Discussion on Formulation of Unintentional Ingredients	Each Product	no	-	Reserved 1/ 2/
163.61-6	Declaration & Certification of Ingredients Limits	Each Product	no	-	Reserved 1/ 2/
163.61-7	Product Analytical Methods & Data	Each Product	no	-	Reserved 1/
163.64	Physical & Chemical Properties	Tech. Grade of A.I.	no	-	Reserved 1/ 2/

These data requirements are current as of September, 1981. Refer to the guidance package for updated requirements.

1. Currently there is no manufacturing-use product for this chemical. Submission of tests normally required of a registered manufacturing-use chemical will not be requested until such a time as the Agency receives an application for registration of a manufacturing-use chemical.

2. These requirements must be fulfilled by each applicant. Data from other applicants may not be cited. Therefore, even if the requirement has been partially or completely fulfilled for some products, no references are given. Except for the above Product Analytical Methods & Data requirement (163.61-7), these requirements must be fulfilled when an application for a manufacturing-use product is received by the Agency.

September, 1981

DATA REQUIREMENTS CHART C

Polyoxyethylene Ethanol Monoesters of 5- (and 6-) Carboxy- 4-Hexyl-2-Cyclohexene-1-Octanoic Acid - Iodine Complex

End-Use Product-Specific Data Requirements: PRODUCT CHEMISTRY

Guidelines Citation	Name of Test	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? If so, due when?
163.61-3	Product Identitiy & Disclosure of Ingredients	Each Product	yes	-	no 2/ 3/ 4/
163.61-4	Description of Manufacturing Process	Each Product	yes	GS-0074-004	no 2/ 3/ 4/
163.61-5	Discussion on Formulation of Unintentional Ingredients	Each Product	no	-	yes/6 months 2/ 3/ 4/
163.61-6	Declaration & Certification of Ingredients Limits	Each Product	no	-	yes/6 months 2/ 3/ 4/
163.61-7	Product Analytical Methods & Data	Each Product	no	-	yes/6 months 2/ 3/
163.64-2	Color	Each Product	yes	-	no 1/ 4/
163.64-3	Physical State	Each Product	no	-	yes/6 months 3/ 4/
163.64-4	Odor	Each Product	no	-	yes/6 months 2/ 3/ 4/
163.64-6	Boiling Point	Each Product	no	-	yes/6 months 2/ 3/ 4/
163.64-7	Density or Specific Gravity	Each Product	yes	-	no 1/ 3/ 4/
163.64-8	Solubility	Each Product	no	-	yes/6 months 2/ 3/ 4/
163.64-9	Vapor Pressure	Each Product	no	-	yes/6 months 2/ 3/ 4/
163.64-11	Octanol/Water Partition Coefficient	Each Product	no	-	yes/6 months 2/ 3/ 4/
163.64-12	pH	Each Product	yes	-	no 1/ 3/ 4/
163.64-13	Stability	Each Product	no	-	yes/6 months 2/ 3/ 4/
163.64-14	Oxidizing/Reducing Action	Each Product	no	-	yes/6 months 2/ 3/ 4/
163.64-15	Flammability	Each Product	no	-	yes/6 months 2/ 3/ 4/
163.64-16	Explosiveness	Each Product	no	-	yes/6 months 2/ 3/ 4/
163.64-17	Storage Stability	Each Product	no	-	yes/6 months 2/ 3/ 4/
163.64-18	Viscosity	Each Product	no	-	yes/6 months 2/ 3/ 4/
163.64-19	Miscibility	Each Product	no	-	yes/6 months 2/ 3/ 4/
163.64-20	Corrosiveness	Each Product	no	-	yes/6 months 2/ 3/ 4/

These data requirements are current as of September, 1981. Refer to the guidance package for updated requirements.

1. The Agency possess information on this subject for the one and only currently registered end-use product. While the Agency has information on on this end-use product, future applications for registration of end-use products containing this chemical must supply these required data.

2. Because the only registered product is produced via an integrated formulation system, the product chemistry data normally required for manufacturing-use products will also be required of this end-use product.

3. Must be supplied on all future end-use products containing this chemical.

4. These requirements must be fulfilled by each applicant. Data from other applicants may not be cited. Therefore, even if the requirement has been partially or completely fulfilled for some products, no references are given. Except for the above Product Analytical Methods & Data requirement (163.61-7), these requirements must be fulfilled when an application for a manufacturing-use product is received by the Agency.

DATA REQUIREMENTS CHART C

Polyoxyethylene Ethanol Monoesters of 5- (and 6-) Carboxy- 4-Hexyl-2-Cyclohexene-1-Octanoic Acid - Iodine Complex

End-Use Product-Specific Data Requirements: TOXICOLOGY

Guidelines Citation	Name of Test	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? If so, due when?
163.81-1	Acute Oral Toxicity	Each Formulation or Substantially Similar Formulations	yes	GS-0074-002,GS-0074-003	no 1/ 2/
163.81-4	Primary Eye Irritation	Each Formulation or Substantially Similar Formulations	yes	GS-0074-002,GS-0074-003	no 1/ 2/
163.81-5	Primary Skin Irritation	Each Formulation or Substantially Similar Formulations	yes	GS-0074-002,GS-0074-003	no 1/ 2/

These data requirements are current as of September, 1981. Refer to the guidance package for updated requirements.

1. The Agency possess information on this subject for the one and only currently registered end-use product. While the Agency has information on on this end-use product, future applications for registration of end-use products containing this chemical must supply these required data.

2. Must be supplied on all future end-use products containing this chemical.

September, 1981

DATA REQUIREMENTS CHART C

Polyoxyethylene Ethanol Monoesters of 5- (and 6-) Carboxy- 4-Hexyl-2-Cyclohexene-1-Octanoic Acid - Iodine Complex

End-Use Product-Specific Data Requirements: EFFICACY

Guidelines Citation	Name of Test	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? If so, due when?

Efficacy data will be reviewed at registration, reregistration or at the time of application for additional anti-microbial claims. Test requirements for food contact surface sanitizers may be found in chapter IX of this Standard.

These data requirements are current as of September, 1981. Refer to the guidance package for updated requirements.

September, 1981

CHAPTER IV: PRODUCT CHEMISTRY

A. Product Chemistry - Manufacturing-Use Product
B. Product Chemistry - End-Use Product
C. Physical and Chemical Properties

The active ingredient consists of a long chain carrier molecule which controls the release of the loosely bound iodine. Since Chemical Abstract Registry (CAS) numbers are assigned to relatively stable molecules and because the iodine associated with the active ingredient readly dissociates from the long chain carrier molecule, no CAS number exists for this compound. The EPA Shaughnessy number is 046924.

A. Product Chemistry - Manufacturing-Use Product

The process(es) by which a technical grade of the active ingredient of polyoxyethylene ethanol monoesters of 5-(and 6-) carboxy-4-hexyl-2-cyclohexene-1-octanoic acid - iodine complex can be synthesized are not available at this time. Polyoxyethylene ethanol monoesters of 5-(and 6-) carboxy-4-hexyl-2-cyclohexene-1-octanoic acid - iodine complex is not made separately as a technical chemical, but only during the production of the formulated product.

B. Product Chemistry - End-Use Product

The central portion of the active ingredient, polyoxyethylene ethanol monoesters of 5-(and 6-) carboxy-4-hexyl-2-cyclohexene-1-octanoic acid, acts as a vehicle for the controlled storage and release of the bactericidal iodine.

According to U.S. patent number 3,917,822 (Turney, MRID GS-0074-004), the formulated product may be produced by the combination of polyethylene glycol monoester of C-21 dicarboxylic acid with iodine, octyl phenol polyethylene oxide condensate and water. The end-use product contains 4.3 percent active ingredient.

C. Physical and Chemical Properties

1. Manufacturing-Use Products

Because no technical product is currently produced, no data are available on the physical and chemical properties of technical polyoxyethylene ethanol monoesters of 5- (and 6-) carboxy-4-hexyl-2-cyclohexene-1-octanoic acid - iodine complex.

2. End-Use Product

A minimum amount of data are available on the physical and chemical properties of the end-use product containing polyoxyethylene ethanol monoesters of 5- (and 6-) carboxy-4-hexyl-2-cyclohexene-1-octanoic acid - iodine complex. The only non-confidential physical and chemical properties for the end-use product is that the available iodine for the end-use product is 1.6%.

CHAPTER V: ENVIRONMENTAL FATE

A. Use Profile
B. Environmental Fate Profile
C. Exposure Profile - End-Use Products

A. Use Profile

This chemical is a sanitizer registered for the control of bacteria on food contact surfaces. A bactericidal concentration of 25 ppm titratable iodine is produced by diluting the 4.3 percent formulated product in water, either manually or in automatic dispensing equipment. Precleaned and wetted food processing equipment is sanitized by either spraying, swabbing or dipping into a solution of 25 ppm titratable iodine. Precleaned and wetted dishes, glasses and utensils are sanitized in automated dishwashing equipment where the formulated product is metered into water that provides a sanitizing rinse of 25 ppm titratable iodine within the dishwasher.

The sanitizing solution is to be prepared fresh each time or discarded, via sanitary sewer, if the titratable iodine residual falls below 12.5 ppm, as determined by a suitable test kit.

Registered Application Rates

Formulation	Site	Type of Application	Rate of Application
4.3% (A.I.)	Food Processing Equipment	Spray or Swab	25 ppm Titratable Iodine
4.3% (A.I.)	Dishes, Glasses & Utensils	Spray, Dip or Swab	25 ppm Titratable Iodine

B. Environmental Fate Profile

Because the indoor uses of this chemical precluded significant environmental exposure, except as a diluted, spent rinsate which drains into the sanitary sewer, the Agency has decided that activated sludge and hydrolysis studies are sufficient to determine the effects of this compound on the environment. No further environmental fate or ecological effects testing is required for the present uses of this chemical. Because of the low production volume, the Agency has further decided to reserve its request for the above environmental fate data until the total production of active ingredient in this and future products containing this chemical reaches 25,000 pounds per year.

C. Exposure Profile End-Use Products

1. Dietary Exposure

As discussed in the Regulatory Rationale section of chapter II of this Standard, the Agency defers the evaluation of risk from dietary exposure to the FDA, as per the December 22, 1971 division of authority cited in 36 FR 24234.

2. Worker Exposure

a. Dermal Exposure

i. Formulated Product Mixing

Several factors contribute to the Agency's conclusion that dermal exposure to the active ingredient in the formulated product will be very low. First, the concentration of the formulated product is small, only 4.3%. Second, to reduce applicator exposure, labeling will require the use of gloves when diluting the formulated product. Third, the staining and irritating nature of the formulated product will encourage careful handling of the product because the formulated product irritates and stains the skin. Spills will be apparent and immediately washed off the skin after future exposures. Fourth, mixing of the use-dilution involves the pouring of a measured amount of the formulated product into water, a process which can normally be done with minimal spillage.

ii. Use-Dilution Product Mixing/Handling

The 4.3% product is diluted 1:697 to make a 25 ppm solution of the iodine complex. This material is then applied to food processing equipment by spraying, swabbing or dipping. The requirement to use gloves while handling the end-use product and its use-dilution will significantly lower exposure during use of this material. Any actual exposure will be very small because of the extremely low concentration of the active ingredient in solution.

b. Ocular Exposure

The Agency has determined that the use of goggles will significantly reduce or eliminate exposure to the formulated product as well as to the diluted product.

c. Inhalation Exposure

i. Formulated Product Mixing

Since the formulated product is an aqueous solution which (1) contains no active or inert ingredient that is volatile and (2) is mixed either in a bucket or dispensed by automated dishwashing equipment, the Agency has determined that very little to no inhalation exposure may be expected to result from mixing of the end-use product in water.

ii. Use Dilution Product Mixing/Handling

Because the vapor pressure of the long chain polymeric carrier either as individual droplets by themselves or contained within water droplets is expected to be extremely low and exposure to a volatilized carrier is unlikely, inhalation of the use dilution is unlikely.

CHAPTER VI: TOXICOLOGY

A. Toxicology Profile
B. Human and Domestic Animal Hazard Assessment

A. Toxicology Profile

1. Manufacturing-Use Product

Because no manufacturing-use product is currently registered or produced, no toxicology data will be requested at this time. Rather, the Agency has decided to reserve the request for acute toxicity, primary irritation and dermal sensitization studies until a manufacturing-use product is produced and/or an application for registration is received.

2. End-Use Product

The toxicity data available for the formulated product are six acute studies: two acute oral LD_{50}'s, two eye irritation studies and two dermal irritation studies.

The acute oral LD_{50} in CF-1 mice of a 1% and 4.3% A.I. formulated product is 24 gm/Kg and 11 gm/Kg, respectively. The low order of acute toxicity in the mouse places the formulated product in toxicity category IV (Latven, MRID GS-0074-002; Latven, MRID GS-0074-003).

Instillation of a 4.3% A.I. formulated product into the eye of albino rabbits produces immediate opacification of the cornea which persists for three days, with inflammation of the conjunctiva persisting in excess of seven days. Instillation of a 1% A.I. formulated product in the eye of albino rabbits produces inflammation and chemosis of the conjunctiva which persists for three days without affecting the cornea or iris. The eye irritation produced in rabbits place the eye irritation potential of both the 1% and 4.3% A.I. formulated product into toxicity category III (Latven, MRID GS-0074-002; Latven, MRID GS-0074-003).

The application of the undiluted 4.3% A.I. formulated product under occlusive covering results in slight edema and deep staining of the skin of albino rabbits, with the stain persisting for more than five days. The application of the undiluted 1% A.I. formulated product under occlusive covering results in no irritation, but slight staining of the skin. The results of the dermal irritation test place both formulations of this chemical in toxicity category IV (Latven, MRID GS-0074-002; Latven, MRID GS-0074-003).

While these studies do not meet the current guidelines requirements for toxicity testing, they are considered sufficient to characterize the 4.3 percent formulated product as having a low order of acute toxicity and a low to moderate irritation potential. The high use dilution is expected to essentially

eliminate any acute toxicity and irritation potential for the use dilution. The Agency has determined that toxicity data on other iodine-based sanitizers is not relevant to the toxicological evaluation of this chemical.

B. Human and Domestic Animal Hazard Assessment

The exposure profile indicates that exposure to the formulated product may occur by the dermal, ocular and dietary routes.

1. Dietary Exposure

The Agency has determined that the dietary exposure to this chemical lies within the purview of section 409 of the Federal Food, Drug and Cosmetic Act because the current uses of this product may result in residues in or on food coming into contact with treated surfaces. A food additive regulation must be obtained for this chemical. This clearance must be obtained: (A) for the use of this chemical as either the sole active ingredient or in combination with other components of a formulation, (B) for use as a sanitizer on industrial food contact surfaces, dishes and utensils, and (C) at levels which are considered to be safe. The Agency, therefore, defers the dietary risk assessment to FDA.

2. Worker Exposure

a. Acute Hazard

The currently registered 4.3% end-use product possesses a low order of oral toxicity, with moderate eye and slight dermal irritating properties, under the conditions of test. No precautionary labeling relative to the oral toxicity is necessary, but this product must bear labeling indicating that it is a slight skin irritant and a moderate eye irritant as well as first aid statements designed to significantly reduce these two hazards. The use of goggles and gloves will reduce the risks from the formulated product. Additionaly, because the active ingredient is very dilute, no acute toxicity or irritation hazard is expected from the use dilution of the formulated product. No further acute testing is required.

b. Chronic Hazard

Because the use of goggles and gloves will significantly reduce exposure to the formulated product and virtually eliminate exposure to the active ingredient in the use dilution of the formulated product, the Agency has determined that the risk will be too low to justify chronic testing.

CHAPTER VII: RESIDUE CHEMISTRY

The Agency has determined that the dietary exposure to this chemical lies within the purview of section 409 of the Federal Food, Drug and Cosmetic Act because the current uses of this product may result in residues in or on food coming into contact with treated surfaces. A food additive regulation (clearance) must be obtained for this chemical. This clearance must be obtained: (A) for the use of this chemical as either the sole active ingredient or in combination with other components of a formulation, (B) for use as a sanitizer on industrial food contact surfaces, dishes and utensils, and (C) at levels which are considered to be safe. The Agency, therefore, defers the dietary risk assessment and necessity for residue data in this risk assessment to FDA.

CHAPTER VIII: ECOLOGICAL EFFECTS

A. Manufacturing-Use Products
B. End-Use Products

A. Manufactureing-Use Products

Because there is currently no registered manufacturing-use product and because end-use products are labeled for indoor use only, no fish and wildlife data are required.

B. End-Use Products

No fish and wildlife data are required to support this end-use product. The formulated product is used indoors, contains only 4.5 percent active ingredient and, when used according to label directions, is diluted at a ratio of 1:657. Therfore, the Agency has concluded that the quantities of active ingredient released into the environment, by sewer systems, will be extremely small and result in no discernable adverse ecological effects.

CHAPTER IX: EFFICACY

The current registered use patterns for polyoxyethylene ethanol monoesters of 5-(and 6-)carboxy-4-hexyl-2-cyclohexene-1-octanoic acid - iodine complex for use as an interior, industrial sanitizer have been found to fall within the public health criteria established under the Agency's efficacy waiver policy, which may be found in a May 11, 1979 Federal Register Notice. (44 FR 27939) Pursuant to this policy the Agency has determined that data requirements shall exist for such instances where "...the continued presence of the target pest organisms may pose a threat to human health, either through direct action or through transmittal of disease." In the case of sanitizers "...all antimicrobial products intended to control microorganisms infectious to man in any area (inanimate surface)" will require efficacy data.

Because the efficacy of sanitizers is frequently affected by the manufacturing process and the confidential inerts of the product, the Agency has concluded that product-by-product review of efficacy is required for sanitizers. Historically, the Agency has required and reviewed product-by-product efficacy data for sanitizers. The Agency recognizes, though, that data on a registered product is also applicable to a repackaged product. The Agency has decided that, in the limited situation where a registrant only repackages another registrant's product, the repackager may substantiate the efficacy of the second product by resubmitting the efficacy data on the first product rather than performing that study again.

The Agency has decided that, except for repackaged products, the efficacy data are product specific and not compensable or interchangable. Antimicrobial efficacy data are not interchangable because the formulation process affects the efficacy of antimicrobial chemicals, the efficacy data for antimicrobials have been reviewed by the Agency for each end-use product. Because efficacy data are product specific, and therefore cannot be routinely cited by other applicants, this Standard will not cite or discuss the existing data for this chemical. Rather, the Standard will specify the tests and acceptance criteria necessary for registration.

A. Test Requirements

Efficacy of sanitizing rinses formulated with iodophors, mixed halides, and chlorine-bearing chemicals must be substantiated with data derived from the AOAC Available Chlorine Germicidal Equivalent Concentration Method (Horowitz, MRID GS-0074-001) Data from one test on each of 3 samples, representing 3 different batches, one of which is at least 60 days old, against Salmonella typhi are required.

B. Performance Standard

Test results must show product concentrations equivalent in activity to 50, 100, and 200 ppm, of available chlorine. (The reference standard is sodium hypochlorite).

CASE BIBLIOGRAPHY

Guide to Use of This Bibliography

1. Content of Bibliography. This bibliography contains citations of all the studies reviewed by EPA in arriving at the positions and conclusions stated elsewhere in this standard. The bibliography alphabetically lists all documents reviewed by the Agency. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions, and the published technical literature.

2. Units of Entry. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to a published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. Identification of Entries. The entries in this bibliography are sorted by author, date of the document, and title. Each entry bears, to the left of the citation proper, a nine-digit numeric identifier. This number is unique to the citations and should be used at any time specific reference is required. This number is called the "Master Record Identifier" or "MRID". It is not related to the six-digit "Accession Number", which has been used to identify volumes of submitted data; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. This is also to be used whenever a specific reference is needed.

4. Form of the Entry. In addition to the Master Record Identifier (MRID), each entry consists of a bibliographic citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submission. The bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs. Some explanatory notes of specific elements follow:

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first known submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. This is the third element in the citation. In some cases it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to us in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submissions:

(1) Submission Date. Immediately following the word 'received' appears the date of the earliest known submission, at the time that particular document was processed into the Pesticide Document Management System.

(2) Administrative Number. The next element, immediately following the word 'under', is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission, at the time that particular document was processed into the Pesticide Document Management System.

(3) Submitter. The third element is the submitter, following the phrase 'submitted by'. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification. The final element in the trailing parenthesis identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol 'CDL', standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th,123456-AA.

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